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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,778	03/03/2006	James A. Fleming III	CRD5013PCT0	6722

27777 7590 04/04/2008  
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EXAMINER
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OU, JING RUI

ART UNIT	PAPER NUMBER
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3773

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,778	<b>Applicant(s)</b> FLEMING III, JAMES A.	
	<b>Examiner</b> JING OU	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/06/2006, 04/06/2007</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This action is responsive to the non-provisional application filed on 06/27/2005.

Claims 1-6 are pending. Claims 1 and 6 are independent.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "30" and "32" have both been used to designate first and second internal space, respectively. However, it appears to be the same internal space in Fig. 3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "curved path" in Claim 2, "guidewire lumen" and "distal guidewire port" in Claim 3, and "one or more market bands" in Claim 5 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

4. The disclosure is objected to because of the following informalities: The "Background" section should be separated from the "Summary of the Invention" section. No new matter should be added.

Appropriate correction is required.

***Claim Objections***

5. Claims 1 and 6 are objected to because of the following informalities: In the second paragraph of Claims 1 and 6, the recitation "internal space" should be replaced by "internal spaces. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to Claims 1 and 6, the "first and second internal spaces" appear to be the same space as shown in Figure 3. It is unclear to the examiner that there are two internal space.

In addition, Claim 1 recites the limitation "the proximal and distal spaces" in paragraph 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

In regard to Claim 2, it is being unclear how the longitudinal axis and the shaft follow a curved path. Examiner interprets the curved path as the curved path of a vessel inside a body.

***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A curved path of a vessel in a body is a non-statutory subject matter.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1, 4, and 6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dulebohn (US Pat. No.: 5,171,314).

In regard to Claims 1, 4 and 6, Dulebohn discloses a surgical snare catheter system, comprising: a flexible shaft (tip, 50, Fig. 12, the tip must be flexible since is used inside a body. Otherwise, it would have be extraordinarily obvious for the tip to be

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flexible to accommodate for the curved environments inside a body, such curved vessels) defining a longitudinal axis having a proximal and a distal end (Figs 1 and 12); the shaft having an opening (side opening, 64, Fig. 12) positioned a distance from the shaft distal end (60, Fig. 12); the longitudinal axis and the shaft follows a curved path (Since the shaft is flexible, it must follow a curved path to get to the target inside the body); the shaft defining an internal space positioned proximally and distally of the opening (the internal space of tip, 50, Fig. 12); a handle (12, Fig. 1) affixed to the shaft near the shaft proximal end (Fig. 1); an actuator (combination of two slides 36 and 38, Fig. 1) coupled with the handle; a retrieval element (wire, 52, Fig. 12) coupled with the actuator (Col. 6, lines 8-15 and Col. 4, lines, 27-36); the retrieval element being longitudinally movable among a range of positions (Col. 6, lines 8-15 and Col. 4, lines, 27-36), including the position of the shaft opening and the positions of the proximal and distal internal spaces (the wire 52 is capable of moving among the position of the shaft opening and the positions of the proximal and distal internal spaces as shown in Fig. 12); a main wire loop coupled with the actuator (Col. 6, lines 12-15, when the first and second end of the wire are attached, a loop is formed engageably with the control member), wherein a distal portion of the shaft has a pre-selected shape (the pre-selected shape of the distal portion of the shaft is closed hemispherical, 62, Fig. 12), such that moving the actuator to a desired position causes the retrieval element to move to a corresponding position (Col. 6, lines 8-15 and Col. 4, lines, 27-36); such that when the retrieval element is in an initial position, the retrieval element is located within the internal space (wire 52 must be located within the internal space of the tip 50); such that

when the actuator is moved to a ready position, the retrieval element protrudes from the shaft opening (Figs 12 and 13);

The recitations, “the retrieval element can be maneuvered to engage a portion of a filter, and then the actuator can be moved to a first or second capture position which pulls the filter through the opening into a selected one of the first and second internal spaces” in Claims 1 and 6 are intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

12. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dulebohn (US Pat. No.: 5,171,314) as applied to claim 1 above, and further in view of Yadav et al (US Pat. No.: 6,391,044).

In regard to Claims 3 and 5, Dulebohn discloses all the limitations of the claims but fails to disclose that the catheter system further comprising a guidewire lumen defined by the shaft, a distal guidewire port near the shaft distal end, and one or more marker bands.

However, Yadav et al explicitly teaches a catheter system, comprising a guidewire lumen (103, Fig. 7) defined by the shaft (catheter, 101, Fig. 7), a distal guidewire port (125, Fig. 7) near the shaft distal end, and one or more marker bands (distal radiopaque marker 176 and proximal radiopaque marker 178, Fig. 14).



Dulebohn and Yadav et al are analogous art because they are from the same field of the endeavor, catheter system for removing objects inside a body.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Dulebohn and Yadav et al before him or her, to modify the catheter system of Dulebohn to include a guidewire lumen defined by the shaft, a distal guidewire port near the shaft distal end, and one or more marker bands as taught by Yadav et al.

The suggestion/motivation for having a guidewire lumen and a distal guidewire port would have been to receive a guidewire into the distal end of catheter (Yadav et al, Col. 7, lines 44-48). Such distal guidewire port can eliminate the need of having a guidewire going through the proximal end of the shaft. Applicant should have noted that it is old and well known in the art that a catheter system comprises one or more marker bands for a surgeon to monitor the location of the catheter inside a body using fluoroscope.

Therefore, it would have been obvious to combine Yadav et al with Dulebohn to obtain the invention as specified in the instant claims.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dulebohn (US Pat. No.: 5,171,314) as applied to claim 1 above, and further in view of Welter et al (US Pat. No. 5,342,371).

In regard to Claim 5, Dulebohn discloses all the limitations of the claim but fails to disclose that the catheter system further comprises one or more marker bands.

However, Welter et al explicitly teaches a catheter system comprising a radiopaque marker band.

Dulebohn and Welter et al are analogous art because they are from the same field of the endeavor, catheter system for removing objects inside a body.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Dulebohn and Welter et al before him or her, to modify the catheter system of Dulebohn to include one or more marker bands as taught by Welter et al.

The suggestion/motivation for doing so would have been to radiographically visualize the distal end of the catheter/elongated member (Welter et al, Col. 2, lines 52-55).

Applicant should have noted that it is old and well known in the art that a catheter system comprises one or more marker bands for a surgeon to monitor the location of the catheter inside a body using fluoroscope.

Therefore, it would have been obvious to combine Welter et al with Dulebohn to obtain the invention as specified in the instant claim.

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Spaulding (US Pat. No.: 5,906,627)

Suon et al (US Pub. No.: 2002/0045918)

Ostrovsky et al (US Pub. No.: 2002/0138097)

McGuckin et al (US Pub. No.: 2002/0193827)

Abe (US Pub. No.: 2002/0188262)

Konya et al (US Pat. No.: 6,517,550)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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